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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,100	06/29/2007	Meiyu Geng	09548.1045USWO	7023

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HAMRE, SCHUMANN, MUELLER & LARSON, P.C.
P.O. BOX 2902
MINNEAPOLIS, MN 55402-0902

EXAMINER	
MAIER, LEIGH C	

ART UNIT	PAPER NUMBER
1623	

MAIL DATE	DELIVERY MODE
12/28/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/594,100	GENG ET AL.	
	Examiner	Art Unit	
	Leigh C. Maier	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-13 and 18-20* is/are rejected.

7)☒ Claim(s) *14-17* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 14 and 18 have been amended. Claims 11-20 are pending.

Any objection or rejection not expressly repeated has been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The declaration under 37 CFR 1.132 filed August 31, 2009 is sufficient to overcome the rejection of claims 11-13, 19 and 20 based upon 35 USC 102(b). The declaration provides data to demonstrate that a product prepared by the method of Marrit (US 6,903,209) differs from the instant product and thus does not anticipate these claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites a composition comprising "an effective amount" of the oligosaccharide product. However, with no stated intended use for the product, one of ordinary skill cannot determine what would be an effective amount.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18 and 20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling the use of the 6-mer in (1) the treatment of type 2 diabetes; (2) the treatment of type 1 diabetes in combination with insulin (but this particular method does not appear to be supported); or (3) the treatment of Alzheimer's disease (AD), does not reasonably provide enablement for the prevention of either type of diabetes or the prevention of AD or treatment for the full scope of oligosaccharides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Many of the factors regarding undue experimentation have been summarized in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Circ. 1988) as follows:

(1) The quantity of experimentation necessary (time and expense);
(2) The amount of direction or guidance presented;
(3) The presence or absence of working examples of the invention;
(4) The nature of the invention;
(5) The state of the prior art;
(6) The relative skill of those in the art;
(7) The predictability or unpredictability of the art; and
(8) The breadth of the claims.

The claims are not particularly broad in scope and one of ordinary skill in the art would be expected to be a highly trained practitioner. However, the prevention of the recited diseases remains problematic and unpredictable.

The instant disclosure demonstrates that the 6-mer has blood glucose lowering capacity in mice having induced diabetes, similar to the effect of dimethyldiguanide (metformin). Davies et

al (Diabetic Medicine, 2004) discusses the difficulties involved in the prevention of diabetes, including the use of pharmaceutical agents. See, particularly the text at pp 405-408 and Table 2. This reference reports spotty positive results using such agents. However, in general, the results are negative. Therefore, there is nothing to suggest that one of ordinary skill would have a reasonable expectation that an agent known to treat type 2 diabetes would also prevent it.

The prevention of type 1 diabetes is even more difficult particularly because it is more difficult to screen and select patients who are at increased risk. See discussion in Skyler et al (Diabetes Care, 2005). This reference finds that the administration of insulin, the standard treatment of type 1 diabetes, does not delay the onset of the disease in relatives of known patients having the disease. There is no evidence that the use of the instant product would have any benefit in the prevention of type 1 diabetes. Further regarding treatment, as noted, insulin is the standard treatment for type 1 diabetes. While a combination of the instant product with insulin, as with metformin and insulin as described by Hamilton et al (Diabetes Care, 2003), might be beneficial to the treatment of type 1 diabetes, there is no evidence that this product would be beneficial to patients in the absence of exogenous insulin.

The prevention of AD is more challenging still. Doraiswamy et al (Exp. Opin. Pharmacother., 2006) discusses the difficulties as length. See particularly sections 2, 3 and 4.10. Although AD is an intensely studied disease, the actual cause remains a mystery, and any potential surrogate biological markers for prevention have not been validated. Prevention trials are expensive and take many years. See section 5.

With respect to the product, the scope comprises oligosaccharides having from 3 to 21 monosaccharides. However, treatment data is presented for the 6-mer only. Without further

information regarding the mechanism of action, there is nothing to suggest that the data for the 6-mer can be extrapolated for the other oligosaccharides.

In view of the foregoing difficulties associated with prevention of the recited diseases, one of ordinary skill would require undue experimentation to implement this method commensurate with its scope.

Claim Rejections - 35 USC § 102

Claims 11-13, 19 and 20 are rejected under 35 U.S.C. 102(a) as being anticipated by Yang et al (Carbohyd. Polym., 2004).

Yang discloses oligomannuronates from alginate degraded by hydrogen peroxide and compositions of these products in water. See abstract; section 2.9; and Figure 2.

Applicant has submitted a translation of the priority document for the instant application. However, the priority document does not support the full scope of the claimed product. The document discloses "a mannuronic acid oligosaccharide." Throughout the reference, the product is referred to as "*the* mannuronic acid oligosaccharide" and "the 6-mer." (emphasis added) Therefore, as far as can be determined, this appears to be limited to the 6-mer and does not support the claimed ranges.

Allowable Subject Matter

Claims 14-17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Yang et al (Carbohyd. Polym., 2004) teaches the preparation of the

recited products as set forth above. See section 3.1. The reference does not teach for fairly suggest the method having a pH adjusting step wherein the pH is adjusted to about 7 between the acid hydrolysis step and oxidative degradation step. Furthermore, a claim drawn to the treatment of type 2 diabetes or AD comprising the administration of an effective amount of the 6-mer oligosaccharide would also be allowable.

Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Thursday and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Anna Jiang at (571) 272-0627, may be contacted. The fax number for Group 1600, Art Unit 1623 is (703) 872-9306.

Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished application is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

/Leigh C. Maier/
Primary Examiner
Art Unit 1623